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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 317

[Docket No. FSIS-2008-0017]

RIN [0583-AD45]

Descriptive Designation for Needle- or blade-tenderized
(Mechanically Tenderized) Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to require the use of the descriptive designation "mechanically tenderized" on the labels of raw or partially cooked needle- or blade-tenderized beef products, including beef products injected with marinade or solution, unless such products are destined to be fully cooked at an official establishment. Beef products that have been needle- or blade-tenderized are referred to as "mechanically tenderized" products. FSIS is proposing that the product name for such beef products include the descriptive designation "mechanically tenderized" and an accurate description of the beef component. By including this descriptive designation consumers will be informed that this product is non-intact. Non-intact products

need to be fully cooked in order to be rendered free of pathogenic bacteria because bacteria may become translocated from the surface of the meat during mechanical tenderization. FSIS is also proposing that the print for all words in the descriptive designation as the product name appear in the same style, color, and size and on a single-color contrasting background. In addition, FSIS is proposing to require that labels of raw and partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions include validated cooking instructions that inform consumers that these products need to be cooked to a specified minimum internal temperature, and whether they need to be held at that minimum temperature for a specified time before consumption, i.e., dwell time or rest time, to ensure that they are fully cooked.

Based on the scientific evidence that indicates that mechanically tenderized beef products need to be cooked more thoroughly than intact beef products, FSIS is proposing these amendments to the regulations.

FSIS is also announcing that it has posted on its Web site guidance for developing validated cooking instructions for mechanically tenderized product. The recommendations in the guidance document are based on the results from published research designed to identify minimum internal temperature and

time combinations sufficient to render a product and studies designed to validate cooking instructions.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER PUBLICATION].

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule and on the guidance for validated cooking instructions. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Docket Clerk, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163B, Washington, DC 20250-3700

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0013. Comments received in response to this docket will be made available for public inspection and posted without change,

including any personal information, to

<http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250-3700; Telephone: (202) 205-0495; Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION:

Executive Summary

Mechanically tenderized beef products are products that have been needle- or blade-tenderized, or have been injected with a marinade or a solution. The act of mechanically tenderizing a beef product potentially pushes pathogens from the exterior of the product into its interior. Because mechanically tenderized beef products are non-intact products, they need to be more fully cooked than intact beef products where potential pathogens are generally limited to the product's surface. The time-and-temperature combination needed to destroy pathogens on the surface of the intact product is less than that necessary to

destroy pathogens that may reside in the interior of the non-intact product.

Requiring mechanically tenderized beef products to be labeled with a descriptive designation that identifies them as mechanically tenderized and accompanied with validated cooking instructions is intended to help inform consumers and instruct them that such products need to be fully cooked.

Under the Federal Meat Inspection Act (FMIA) the labels of meat products must be truthful and not misleading, and the labels must accurately disclose to consumers what they are buying when they purchase any meat product. The FMIA gives FSIS broad authority to promulgate rules and regulations necessary to carry out its provisions.

FSIS is proposing that the labeling of raw or partially cooked mechanically tenderized beef products bear a descriptive designation that clearly identifies that the product has been mechanically tenderized, unless such product is destined to be fully cooked in an official establishment.¹

To ensure that the descriptive designation is readily apparent on the label, FSIS is proposing that the print for all words in the descriptive designation, as well as the words in the description of the product, appear in the same font style,

¹Any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under [FSIS] regulations (9 CFR 301.2).

color, and size as the product name and on a single-color contrasting background.

FSIS is also proposing to require that labels of raw and partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants and similar institutions include cooking instructions that have been validated to ensure that a sufficient number of potential pathogens throughout the product are destroyed. FSIS will provide a Compliance Guide to help establishments develop validated cooking instructions.

Table 1: Summary of Estimated Costs and Benefits

Estimated Quantified Benefits, Costs, and Net Benefits^a			
	Benefits^b	Costs	Net Benefits
If this proposed rule is finalized <u>after</u> the final rule for products with added solutions	\$1,511,000 (\$121,000 to \$11,641,000)	\$140,000 ^c	\$1,371,000 (-\$19,000 to \$11,501,000)
If this proposed rule is finalized <u>before</u> the final rule for products with added solutions	\$1,511,000 (\$121,000 to \$11,641,000)	\$349,000 ^d	\$1,162,000 (-\$228,000 to \$11,292,000)
Non-Quantified Benefits and Costs			
	Benefits	Costs	
	<ul style="list-style-type: none"> • Truthful and accurate labeling • Increased public awareness of product identities • Better market information to consumers • Increased producer surplus to producers who sell intact beef or other meats consumers may substitute for mechanically- 	<ul style="list-style-type: none"> • Cost to validate cooking instructions • Loss in producer surplus to producers who sell mechanically tenderized beef. • Loss in consumer surplus to consumers who start cooking their beef to a higher temperature, which they prefer less than cooking rare. • Loss in consumer surplus to consumers 	

	tenderized beef.	<p>who might substitute other meats or other cuts of meat, which they prefer less.</p> <ul style="list-style-type: none"> Costs incurred by food service providers that change their standard operating procedures related to intact and mechanically-tenderized beef. 	
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^a Annualized over 10 years at a 7 percent discount rate.

^b Assumes that on the low end, 15% of consumers and 0% of food service providers will use validated cooking instructions and using the lower bound of the credibility interval from Scallan while on the high end, 56% of consumers and 100% of food service providers and using the upper bound of the credibility interval from Scallan will use validated cooking instructions, with an average estimate of 24% for consumers and 24% for food service providers.

^c Estimated costs fall to \$120,000 and net benefits rise by \$20,000 when annualized with a 3 percent discount rate.

^d Estimated costs fall to \$298,000 and net benefits rise by \$51,000 when annualized with a 3 percent discount rate.

Source: FSIS Policy Analysis Staff

Background

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601-695, at 21 U.S.C. 607) provides for the approval by the Secretary of Agriculture of the labels of meat and meat food products before these products can enter commerce. The FMIA also prohibits the distribution in commerce of meat or meat food products that are adulterated or misbranded.

The FMIA provides that a product is misbranded if its labeling is false or misleading in any particular, or if it is offered for sale under the name of another food (21 U.S.C. 601(n)(1), 601(n)(2)). Thus, under the FMIA, the labels of meat or meat food products must be truthful and not misleading, and the labels must accurately disclose to consumers what they are buying when they purchase any meat product. The FMIA gives FSIS

broad authority to promulgate rules and regulations necessary to carry out its provisions (21 U.S.C. 621).

To prevent meat or meat food products from being misbranded, the meat inspection regulations require that the labels of meat products contain specific information and that such information be displayed as prescribed in the regulations (9 CFR part 317). Under the regulations, the principal display panel on the label of a meat product must include, among other information, the name of the product. For products that purport to be or are represented by a regulatory standard of identity, the name of the product on the label must be the name of the food specified in the standard. For any other product, the name on the label must be "the common or usual name of the food, if any there be." If there is no common or usual name, the name on the label must be a "truthful, descriptive designation" (9 CFR 317.2(c)(1)). In addition, the meat inspection regulations require that the descriptive designations for products that have no common or usual name completely identify the product, including the method of preparation, such as salting, smoking, drying, cooking, or chopping, unless the product name implies, or the manner of packaging shows, that the product was subject to such preparation (9 CFR 317.2(e)).

Petition Related to Mechanically Tenderized Products

In 2009, the Safe Food Coalition sent a petition to the Secretary of Agriculture to request, among other issues, regulatory action to require that the labels of mechanically tenderized beef products disclose the fact that the products have been mechanically tenderized. The petition stated that, (1) consumers and restaurants do not have sufficient information to ensure that these products are cooked safely because FSIS does not provide recommended cooking temperatures for mechanically tenderized products, (2) the recommended cooking temperatures for intact products are not appropriate for non-intact, mechanically tenderized products, and (3) a labeling requirement for mechanically tenderized products is critical for consumers and retail outlets, so that they have the information necessary to safely prepare these products.

In June 2010, the Conference for Food Protection (CFP) petitioned FSIS to issue a mandatory labeling provision for mechanically tenderized beef that would require labels to specify that a cut has been mechanically tenderized. The petition stated that mechanically tenderized beef, especially when frozen, could be mistakenly perceived by consumers to be a whole, intact muscle cut. The petition asserted that without clear labeling, food retailers and consumers do not have the information necessary to prepare these products safely. According to the petition, if labeling does not indicate that

the product is mechanically tenderized, consumers are not aware of the potential risk created when these products are less than fully cooked. The petition stated that mandatory labeling of these products would reduce the number of foodborne illnesses in the United States.

Mechanically Tenderized Beef

Mechanically tenderized beef products are products that have been needle- or blade-tenderized, or have only been injected with a marinade or solution. FSIS has previously described mechanically tenderized beef products in this manner, notably in its Federal Register notice, HACCP Plan Reassessment for Mechanically Tenderized Beef Products (May 26, 2005; 70 FR 30331). FSIS is asking for comment on this definition of mechanically tenderized beef products and on whether it should be incorporated into the regulations.

Consumers consider product tenderness to be a key factor when purchasing meat products, and the tenderness of a roast or steak is a key selling point for the meat industry. The tenderness of a meat product depends on the cut of the meat, and there are various techniques that companies can use to improve the tenderness of the less tender cuts, including mechanical tenderization.

The mechanical tenderization process involves piercing the product with a set of needles or blades, which breaks up muscle

fiber and tough connective tissue, resulting in increased tenderness.² Research has shown that needle or blade mechanical tenderization can improve the tenderness of less tender, and typically less expensive, beef cuts.^{3,4,5,6} The process makes the less tender cuts of beef more marketable to consumers.

An increasing number of establishments use mechanical tenderization processes for beef.⁷ The mechanically tenderized products are widely available to consumers in the marketplace.

Mechanically tenderized products are referred to as "non-intact" and have different physical attributes than intact, non-tenderized products. A beef product that has been subjected to the mechanical tenderization process is more tender than it would have been had it not been mechanically tenderized, but it

² Maddock, Robert 2008. Mechanical Tenderization of Beef, National Cattleman's Beef Association.

³ Jeremiah, L.E., L.L. Gibson, B. Cunningham 1999. The Influence of Mechanical Tenderization on the Palatability of Certain Bovine Muscle Food Research International 32: (585-591).

⁴ Pietrasik, Z., Shand, P.J. 2004. Effect of Blade Tenderization and Tumbling Time on the Processing Characteristics and Tenderness of Injected Cooked Roast Beef. Meat Science 66: (871-879).

⁵ King, D.A., Wheeler, T.L. Shackelford, S.D., Pfeiffer, K.D., Nickelson, R., Koolmaraie, M. 2009. Effect of Blade Tenderization, Aging Time, and Aging Temperature on tenderness of Beef Lumborum and Gluteus Medius. J. Animal Science 97: (2962-2960).

⁶ Pietrasik, Z., Aslhus, J.L., Gibson, L.L., Shand, P.J. 2010. Influence of Blade Tenderization, Moisture Enhancement and Pancreatin Enzyme Treatment on the Processing Characteristics and Tenderness of Beef Semitendinosus Muscle. Meat Science 84: (512-517).

⁷ According to FSIS's Checklist and Reassessment of Control for E. coli O157:H7 in Beef Operations, 850 of 2323 establishments indicated that they had a mechanical tenderizing operation, http://www.fsis.usda.gov/PDF/Ecoli_Reassement_&Checklist.pdf. In addition, a 2003 National Cattleman's Beef Association survey found that 188 of 200 processors used mechanical tenderization, <http://docserver.ingentaconnect.com/deliver/connect/iafp/0362028x/v71n11/s4.pdf?expires=1300291287&id=61762965&titleid=5200021&accname=NAL-Group3&checksum=57C4A9F3F73D2022F0EEFFA2568826BF>.

is no longer an intact cut of meat. Significantly, products that have been needle- or blade-tenderized are typically indistinguishable in appearance from whole, intact products. Furthermore, under the current regulatory approach, intact and mechanically tenderized beef products are permitted to have the same product name, and products that have been mechanically tenderized need not disclose this fact in their labeling. Thus, the labeling of mechanically tenderized beef products is not required to reveal a significant material fact about the nature of the product. Without information about this fact on the product labeling, consumers and industry may be purchasing these products without knowing that they have been needle- or blade-tenderized.

Since 2000, the Centers for Disease Control and Prevention has received reports of six outbreaks attributable to needle- or blade-tenderized beef products prepared in restaurants and consumers' homes. The outbreaks included steaks that were mechanically tenderized with added solutions and one outbreak involving mechanically tenderized steaks in which no information was available concerning whether the product contained added solutions. Among these outbreaks, there were a total of 176

Escherichia coli (E. coli) O157:H7 cases that resulted in 32 hospitalizations and 4 cases of hemolytic uremic syndrome (HUS).⁸

Table 2. Outbreaks Linked to Tenderized/Marinated Steaks Originating in the United States (Compilation of FSIS Generated Data)

Year	Product	Case Patients/ Epi. Link	Hospitalizations / Deaths	FSIS Recall number
2009	Blade tenderized steaks, vacuum tumbled with marinade	25/17-steak	10/1 ^a	067-2009 (USDA-FSIS, 2009)
April–May 2007	Needle injected and marinated steaks	8/8	6/0	019-2007 (USDA-FSIS, 2007)
May–Aug. 2007	Needle tenderized, seasoned tri-tip beef	124/124	8/0	No Recall ^{b,c}
July–Aug. 2004	Blade tenderized steaks exposed to marinade in vacuum tumbler	4/4	1/0	033-2004 (USDA-FSIS, 2004)
May–June 2003 (Laine et al., 2005)	Bacon wrapped steaks, mechanically tenderized, injected flavoring	13/13	7/0	028-2003 (USDA-FSIS, 2003)
Aug. 2000	Needle tenderized	2/2	0/0	No Recall ^{d,e}
Total		176/168	32/1	

a. Patient who died did not eat steak.

b. Illnesses were all associated with product served through the restaurant/food-to-go operation that had some sanitary violations.

c. Notes indicate that a seasoning/marinade was used in the needling process.

d. Unknown whether solution was added

e. FSIS was not involved in the original investigation.

Five of the six outbreaks listed in Table 2 had solutions added to the tenderized beef. These five outbreaks accounted for 174 of the 176 illnesses. The remaining two illnesses occurred in an outbreak in which steak was mechanically tenderized, but it was not known if solution was added.

Follow up investigations suggested that failure to fully cook a mechanically tenderized raw or partially cooked beef

⁸ Compilation of USDA-FSIS Data, 2010

product was likely a significant contributing factor in all of these outbreaks. In many cases, patients associated with outbreaks reported preparing or ordering steaks as "rare" or "medium-rare."^{9, 10} Published research suggests that pathogens can be translocated from the surface of mechanically tenderized beef products to the interior during processing because of the piercing of the beef by the needle or blade.¹¹ The potential for translocation of pathogens to the interior of the product suggests that the interior of mechanically tenderized beef would need to be more fully cooked than a piece of intact beef with a similar amount of pathogens only on the surface.¹²

This research led FSIS to recommend on its Web site that mechanically tenderized beef products should be cooked to 145°F with a three-minute dwell time because it will result in a 5.0-log reduction of Salmonella throughout the product.^{13,14}

⁹ Culpepper, W., Ihry, T., Medus, C., Ingram, A., Von Stein, D., Stroika, S., Hyytia-Trees, E., Seys, S., Sotir, M.J. 2010. Multi-state outbreak of Escherichia coli O157:H7 infections associated with consumption of mechanically-tenderized steaks in restaurants - United States, 2009. Presented at International Association for Food Protection; August 1-4, 2010; Anaheim, CA.

¹⁰ Haubert, N., Cronquist, A., Parachini, S., Lawrence, J., Woo-Ming, A., Volkman, T., Moyer, S., Watkins, A. 2006. Outbreak of Escherichia coli O157:H7 Associated with Consuming Needle Tenderized Undercooked Steak from a Restaurant Chain - Denver Area, Colorado, 2004. Presented at International Conference of Emerging Infectious Diseases; March 19-22, 2006; Atlanta, GA.

¹¹ Luchansky, JB, Phebus RK, Thippareddi H, Call JE 2008. Translocation of surface-inoculated Escherichia coli O157:H7 into beef subprimals following blade tenderization. J. Food Prot. 2008 Nov.; 71(11):2190-7

¹² Sporing, Sarah B. 1999. Escherichia coli O157:H7 Risk Assessment for Production and Cooking of Blade Tenderized Beef Steak. Thesis. Kansas State University.

¹³ <http://askfsis.custhelp.com/ci/fattach/get/4648/>.

Salmonella is an indicator for lethality because it is more heat-resistant than other pathogens such as E. coli O157:H7. Therefore, if a 5.0- log reduction of Salmonella is achieved, at least a 5-log reduction of E. coli O157:H7 should be achieved as well¹⁵.

Consumers often prefer to eat their steaks "rare" or "medium rare." Generally, intact cuts of muscle such as steaks should be free of pathogenic bacteria such as E. coli O157:H7 and other Shiga-toxin producing E. coli (STEC) organisms if cooked to these desired levels of doneness because contamination with pathogenic bacteria, if present, would likely only occur on the surface of the product. The National Advisory Committee on Microbiological Criteria for Foods (1997) stated that "due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change".¹⁶ To date, no outbreaks or

¹⁴ Goodfellow, S. J. and Brown, W. L. 1978. Fate of *Salmonella* Inoculated into Beef for Cooking. *J. of Food Protect.* 41: (598-605).

¹⁵ Line, J.E., Fain, A.R., Moran, A.B., Martin, L.M., Lechowich, R.V., Carosella, J.M., and Brown, W.L. 1991. Lethality of heat to Escherichia coli O157:H7: D-value and Z-value determinations in ground beef. *J Food Protect.* 54: (762-766).

¹⁶ National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1997. Recommendations for Appropriate Cooking Temperatures for Intact Beef Steaks & Cooked Beef Patties for the Control of Vegetative Enteric Pathogens. U.S. Department of Agriculture, Food Safety and Inspection Service, Washington, DC.

sporadic illnesses from consuming intact product have been reported to CDC.¹⁷

Descriptive Designation

FSIS has carefully considered the available information on mechanically tenderized beef, including the petitions submitted by the Safe Food Coalition and by CFP, and has concluded that without specific labeling, raw or partially cooked mechanically tenderized beef products could be mistakenly perceived by consumers to be whole, intact muscle cuts. The fact that a cut of beef has been needle- or blade-tenderized is a characterizing feature of the product and, as such, a material fact that is likely to affect consumers' purchase decisions and that should affect their preparation of the product. The literature suggests that many consumers are aware of and a portion of these read the safe handling instructions labels, and reported changing their meat preparation methods because of the labels.¹⁸

¹⁹ ²⁰ ²¹ ²² ²³ Because of the likelihood that illness rates would

¹⁷ National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1997. Recommendations for Appropriate Cooking Temperatures for Intact Beef Steaks & Cooked Beef Patties for the Control of Vegetative Enteric Pathogens. U.S. Department of Agriculture, Food Safety and Inspection Service, Washington, DC.

¹⁸ Yang et al (1999) show that 15% of consumers changed their behavior based on reading safe handling instruction labels. (Evaluation of Safe Food-Handling Instructions on Raw Meat and Poultry Products. J of Food Protect. 63: (1321-1325.)

¹⁹ Bruhn (1997) shows that 17% of consumers changed their behavior based on reading safe handling instructions. Consumer Concerns Motivating to Action, Emerging Infectious Diseases. 3(4): 511-515.

be reduced if more specific labeling were required, FSIS proposes that the labeling of raw or partially cooked mechanically tenderized beef products bear a descriptive designation that clearly identifies the product has been mechanically tenderized unless such product is destined to be fully cooked in an official establishment. The proposed descriptive designation will provide household consumers, official establishments, restaurants, and retail stores with the information they need to identify whether a cut of beef is an intact, non-tenderized product, or whether it is a non-intact, mechanically tenderized product. Should this rule become final, FSIS will conduct a public education campaign to explain the significance of the term "mechanically tenderized" to consumers.

FSIS is proposing that if raw or partially cooked mechanically tenderized beef product is destined to be fully cooked at an official establishment, the descriptive designation would not be required on the product label. Therefore, if one establishment produces raw or partially cooked product and sends

²⁰ Adul-Nyako et al (2003) show a significant positive influence of labels on safe handling practices. Safe Handling Labels and Consumer Behavior in the Southern U.S.

²¹ Cates, Sheryl C., Cignetti, Connie, Kosa, Katherine M. March 22, 2002. RTI: Consumer Research on Food Safety Labeling Features for the Development of Responsive Labeling Policy.

²² Cates, Sheryl C., Cignetti, Connie, Kosa, Katherine M. March 22, 2002. RTI: Consumer Research on Food Safety Labeling Features for the Development of Responsive Labeling Policy.

²³ Cates, Sheryl C., Carter-Young, Heather L., Gledhill, Erica C. April 25, 2001. RTI: Consumer Perceptions of Not-Ready-to-Eat Meat and Poultry Labeling Terminology.

it to a second establishment for cooking, the first establishment would not be required to include the descriptive designation on the product label.

The descriptive designation that FSIS is proposing would only apply to raw or partially cooked beef products that have been needle tenderized or blade tenderized, including beef products injected with marinade or solution. Other tenderization methods such as pounding and cubing change the appearance of the product, putting consumers on notice that the product is not intact. Additionally, a majority of establishments already identify products that have been cubed on the label.

FSIS is proposing to require that the label of needle- or blade-tenderized beef products contain the designated description "mechanically tenderized" because this term accurately and truthfully describes the nature of the product. Additionally, this term clearly and completely identifies the preparation process that the product underwent. FSIS's goal is to choose a term that will not affect consumers' perception of the quality, or cost, of the product. Rather, FSIS sought to simply differentiate mechanically tenderized beef products from non-tenderized, intact beef products. The term "mechanically tenderized" is non-technical and likely will be understood by consumers, restaurants, retail stores, and official

establishments, although FSIS is taking comment on this assumption.

To ensure that the descriptive designation is readily apparent on the label, FSIS is proposing that the print for all words in the descriptive designation, as well as the words in the description of the product, appear in the same font style, color, and size as the product name and on a single-color contrasting background.

At this time, FSIS is not proposing similar labeling requirements for mechanically tenderized poultry products or for other mechanically tenderized meat products, such as pork. While FSIS has the checklist data discussed above for beef products, FSIS does not have similar data for other products necessary to assess production practices for mechanically tenderized products. There have been no known outbreaks for mechanically tenderized poultry or non-beef products.

FSIS is not proposing to require the descriptive designation on needle- or blade-tenderized beef products that are fully cooked in an official establishment because such products do not pose the same pathogen hazard as the raw or partially cooked products. Further, consumers can recognize that a product has been cooked. FSIS requests comment on whether it should require fully cooked needle- or blade-

tenderized beef products to have the descriptive designation on their labels.

Validated Cooking Instructions for Raw and Partially Cooked Mechanically Tenderized Products

FSIS is proposing to amend the regulations to require validated cooking instructions on the labels of mechanically tenderized beef products. Under current regulations, to prevent raw and partially cooked meat products from being misbranded, the labels of all meat products, including those that have been mechanically tenderized, are required to include safe handling instructions as prescribed in 9 CFR 317.2(l). These regulations require that the labels of raw and partially cooked meat that are not intended for further processing at an official establishment include the statement: "This product was prepared from inspected and passed meat and/or poultry. Some food product may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions" (9 CFR 317.2(l)(2)). One of the instructions required under the regulations is to "cook thoroughly" (9 CFR 317.2(l)(3)(iii)).

Although the safe handling instructions in the regulations include "cook thoroughly" in the labeling of raw and partially cooked meat and poultry products, the regulations do not require that these instructions specify the dwell time or

internal temperature parameters required to ensure that the product is fully cooked. Because mechanically tenderized products have the same appearance as intact products, household consumers, hotels, restaurants, and similar institutions may incorrectly assume that mechanically tenderized products may be prepared similarly to intact products (i.e., that it is ok to cook the product "rare" or "medium-rare"), even if the product label shows that the product is mechanically tenderized. This increases the likelihood that household consumers, hotels, restaurants, and similar institutions will undercook a mechanically tenderized product.

Despite the safe handling instructions to "cook thoroughly," recent outbreak data suggest that for needle- or blade-tenderized raw beef products, consumers, restaurants, and retail stores do not always fully cook these products using a temperature-and-time combination sufficient to destroy harmful bacteria, such as *Escherichia coli* O157:H7 (*E. coli* O157:H7), in the product. CDC and other governmental investigators have found that failure to fully cook a mechanically tenderized raw or partially cooked beef product was likely a significant contributing factor in the outbreaks.^{24,25} In many cases,

²⁴ Swanson, L. E., Scheftel, J.M., Boxrud, D.J., Vought, K.J., Danila, R.N., Elfering, K.M., and Smith, K.E. 2005. Outbreak of *Escherichia coli* O157:H7 infections associated with nonintact blade-tenderized frozen steaks sold by door-to-door vendors. J. Food Prot 68:(1198-1202).

patients reported preparing or ordering steaks as "rare" or "medium rare."

Because restaurants may not know that products are mechanically tenderized, they may prepare for their customers mechanically tenderized beef products that are "rare" or "medium-rare." Indeed, their customers may ask them to do so. Research on the sensory and cooking characteristics of various beef cuts suggests that the palatability of beef cuts decreases as the internal endpoint temperature increases. Other research has shown that consumers tend to prefer beef products that are cooked to a lower degree of doneness than that needed to reach the necessary internal temperature for a mechanically tenderized product, which needs to be fully cooked throughout its interior.²⁶ In some studies, consumers have given highest ratings to such underdone beef products.^{27,28,29} Consumers thus

²⁵ Culpepper W, Ihry T, Medus C, Ingram A, Von Stein D, Stroika S, Hyytia-Trees E, Seys S, Sotir MJ. 2010. Multi-state outbreak of Escherichia coli O157:H7 infections associated with consumption of mechanically-tenderized steaks in restaurants - United States, 2009. Presented at International Association for Food Protection; August 1-4, 2010; Anaheim, CA.

²⁶ Schmidt, T.B., Keene, M.P, and Lorenzen, C.L. 2002. Improving Consumer Satisfaction of Beef Through the use of Thermometers and Consumer Education by Wait Staff. J. Food Sci. 67: (3190-3193).

²⁷ Lorenzen, C.L., T.R. Neely, R.K. Miller, J.D. Tatum, J.W. Wise, J.F. Taylor, M.J. Buyck, J.O. Reagan, and J.W. Savell. 1999. Beef Customer Satisfaction: Cooking Methods and Degree of Doneness Effects on the Top Loin Steaks. J. Animal Science 77:637-644.

²⁸ Savell, J.W. , Lorenzen,C.L., Neely,T.R., Miller,R.K., Tatum,J.D., Wise,J.W., Taylor,J.F., Buyck,M.J., Reagan, J.O. 1999. Beef Customer Satisfaction: Cooking Methods and Degree of Doneness Effects on the Top Sirloin Steaks. J. Animal Science 77:645-652.

²⁹ Neely, T.E., Lorenzen,C.L., Miller,R.K., Tatum,J.D., Wise, J.W.,Taylor, J.F., Buyck,M.J., and Savell, J.W.. 1999. J. Animal Science 77:653-660.

may order steaks that are cooked to a lesser degree of doneness than that necessary to fully cook them and restaurateurs may consequently serve the less-done products. FSIS requests comments on how the proposed labeling changes are likely to impact restaurants and other food service operations.

On the basis of these studies, scientific evidence referred to earlier in this document, and other studies^{30,31,32} that indicate that mechanically tenderized beef products need to be cooked more thoroughly than intact beef products, FSIS is making an additional proposal. Thus, in addition to a descriptive designation that identifies that needle- or blade-tenderized beef products have been mechanically tenderized, FSIS is proposing to require that labels of raw and partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants and similar institutions include cooking instructions that have been validated to ensure that potential pathogens throughout the product are destroyed.

Under this proposal, needle- or blade-tenderized beef

Beef Customer Satisfaction: Cooking Method and Degree of Doneness Effects on the Top Round Steak.

³⁰ Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Call, J.E., Schlosser, W., Shaw, W., Bauer, N., Latimer, H. 2012. Fate of Shiga toxin-Producing O157:H7 and non-O157:H7 *Escherichia coli* Cells within Blade-Tenderized Beef Steaks after Cooking on a Commercial Open-Flame Gas Grill. J. of Food Protect 75: (62-70).

³¹ Johnston, R.W., M.E. Harris, A.B. Moran. 1978. The Effect of Mechanically Tenderization on Beef Rounds Inoculated with Salmonella. J. Food Safety 1:201-209.

³² Johnston, R.W., M.E. Harris, A.B. Moran. 1978. The Effect of Mechanically Tenderization on Beef Rounds Inoculated with Salmonella. J. Food Safety 1:201-209.

products that are destined to be fully cooked at an official establishment would not be required to include validated cooking instructions on product labels. Official establishments are required to follow regulatory performance standards to ensure that ready-to-eat products receive a full lethality treatment (for cooked beef, roast beef, and cooked corned beef products, see 9 CFR 318.17) and use controls to prevent post-lethality contamination with Listeria monocytogenes (9 CFR 430.4).

FSIS is proposing to require that the validated cooking instructions include, at a minimum: (1) the method of cooking; (2) a minimum internal temperature validated to ensure that potential pathogens are destroyed throughout the product; (3) whether the product needs to be held for a specified time at that temperature or higher before consumption; and (4) instruction that the internal temperature should be measured by the use of a thermometer. The Agency is proposing to require that the cooking instruction statement include the cooking method because consumers need explicit information about how to cook a product in order to ensure that it is safe for consumption. The cooking instructions included on the label should be practical and likely to be followed by consumers. FSIS is proposing that cooking instructions must be validated to ensure that potential pathogens are destroyed throughout the product as determined by the specified minimum internal

temperature and dwell time for the product before consumption.

Consistent with the regulation on HACCP validation (9 CFR 417.4), to validate the cooking instructions, should this rule become final, the establishment would be required to obtain scientific or technical support for the judgments made in designing the cooking instructions, and in-plant data to demonstrate that it is, in fact, achieving the critical operational parameters documented in the scientific or technical support. HACCP does not require establishments that produce mechanically tenderized product to have validated cooking instructions. But just as establishments have to validate their HACCP plans' adequacy in controlling the food safety hazards identified during the hazard analysis, so too, under this proposed rule, establishments that produce mechanically tenderized beef products will have to validate their cooking instructions. The scientific support would need to demonstrate that: (1) the cooking instructions provided can repeatedly achieve the desired minimum internal temperature and, if applicable, rest time and (2) the minimum internal time and, if applicable, rest time achieved by the instructions will ensure that the product is fully cooked to destroy potential pathogens throughout the product. The in-plant data would need to demonstrate that the establishment is, in fact, achieving the critical operational parameters documented in the scientific or

technical support. For additional information on validation see the following Federal Register notice on HACCP Systems Validation (77 FR 27135; May 10, 2012) available at:
<http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2009-0019.htm>.

Guidance on Validated Cooking Instructions

The Agency has posted on its Significant Guidance Documents Web page

(http://www.fsis.usda.gov/Significant_Guidance/index.asp)

guidance on validated cooking instructions for mechanically tenderized product. This guidance, drawing heavily on the findings of the two recent ARS studies (Luchansky 2011 and 2012) represents current FSIS thinking; however, FSIS requests comment on it and intends to update it as necessary before this rule becomes final. In addition to requesting comments on the guidance document, FSIS specifically requests additional scientifically valid data on cooking instructions developed for various mechanically tenderized beef products that have been found to consistently meet an endpoint temperature and rest time sufficient to ensure the product is fully cooked.

Should this rule become final, establishments could collect their own scientific data to support the cooking instruction, use a study from an outside source, or use the guidance provided by FSIS. The guidance document provided by FSIS includes a

summary of cooking instructions (e.g., place product in an oven heated to X degrees F for X minutes to achieve the desired endpoint temperature of X degrees F for X minutes) drawn from the peer reviewed literature to achieve endpoint temperatures sufficient to ensure the product is fully cooked and the risk of contamination with a pathogen is sufficiently reduced. The format and wording of the instructions are based on best practices seen by the FSIS Labeling and Program Delivery Division (LPDD). The critical operational parameters from each study (e.g., the cut of meat, method of tenderization, product thickness, and cooking method) are included in the summary so that establishments can select cooking instructions that will be applicable to their product. Establishments could utilize these cooking instructions on the labels of their products, without needing to conduct any additional experiments or provide any further scientific support, provided that the actual product being produced and labeled is similar to the product the instructions were developed for.

In the event that establishments are unable to use the specific examples in the guidance (e.g., because the product is of a different thickness or is to be cooked using a different method than was previously studied), the guidance document also contains instructions on how to develop such support. The protocol provided is based on the experimental design employed

in the recent ARS studies. Specifically, the document addresses the factors that should be considered when designing a validation study (e.g., number of replicates, factors that affect heat transfer, testing methodology, etc.).

Affected Industry

The proposed new descriptive designation requirement would apply to all raw or partially cooked needle- or blade-tenderized beef products going to retail stores, restaurants, hotels, or similar institutions or to other official establishments for further processing other than cooking. The proposed requirements for validated cooking instructions would apply to raw or partially cooked mechanically tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions. If a second establishment repackages the product for household consumers, hotels, restaurants or similar institutions, the second establishment would be responsible for applying the validated cooking instructions to the product label. If retail stores repackage the product, they would be required to include the descriptive designation and validated cooking instructions from the official establishment on the retail label.

If this proposal is adopted as a final rule, establishments or retail stores would be permitted to add the required information to existing label designs, or they could apply a

separate sticker with the required information to existing labels. FSIS would generically approve the modifications made to the labels for needle- or blade-tenderized beef products from official establishments based on the provisions for generic approval in 9 CFR 317.5(a)(1).

If this proposal is finalized, raw or partially cooked needle- or blade-tenderized beef products would have descriptive designations that are different from those of whole, intact products. Once implemented, raw or partially cooked beef products subject to this rule whose labels do not include the descriptive designation "mechanically tenderized," and such products destined for household consumers, hotels, restaurants, or similar institutions whose labels do not include validated cooking instructions, would be misbranded because the product labels would be false or misleading, because the products would be offered for sale under the name of another food, and because the product labels would fail to bear the required handling information necessary to maintain the products' wholesome condition (21 U.S.C. 601(n)(1), 601(n)(2), and 601(n)(12)).

Of the 555 official establishments that produce mechanically tenderized beef products that could be affected by this proposed rule, 542 are small or very small according to the FSIS HACCP definition. There are about 251 very small establishments (with fewer than 10 employees) and 291 small

establishments (with more than 10 but less than 500 employees). Therefore, a total of 542 small and very small establishments could possibly be affected by this rule. The FSIS HACCP definition assigns a size based on the total number of employees in each official establishment. The Small Business Administration definition of a small business applies to a firm's parent company and all affiliates as a single entity. These small and very small manufacturers, like the large manufacturers, would incur the costs associated with modifying product labels to add on the labels "mechanically tenderized" and validated cooking instructions needed to ensure adequate pathogen destruction.

Descriptive Designations on Intact Product

Note that intact beef products may bear a descriptive designation of "intact," consistent with 9 CFR 317.2(e). However, such a descriptive designation is not required. If producers want to use such a descriptive designation on labels of intact product to distinguish it from non-intact product, FSIS would allow the designation and would not consider it a special statement requiring label approval by the Agency. Rather, FSIS would generically approve the labels with the statement based on the provisions for generic approval in 9 CFR 317.5(a)(1).

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this proposed rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted, (2) no retroactive effect will be given to this rule, and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated an "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Baseline: The Final Report of the Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry

Product, February 2012 (February 2012 Report),³³ estimates that there are 555 official establishments that produce blade, needle, and both blade and needle mechanically tenderized beef products.³⁴ In terms of assigned HACCP processing size, the 555 establishments are comprised of 251 very small, 291 small, and 13 large establishments. Total U.S. beef production was 24.3 billion pounds in 2010.³⁵ The February 2012 Report estimates that the proportion of beef products that is mechanically tenderized is about 10.5 percent of total beef products sold, or 2.6 billion pounds. Of these products, an estimated 318 million pounds were brand name packaged by the establishment for retail sales; 640 million pounds private label packaged by the establishment for retail sales; 1,594 million pounds were packaged by the establishment for food service, and 479 million pounds were packaged in retail operations.³⁶

Retail establishments would be involved in repackaging products to be sold at retail. FSIS has not estimated the

³³ Muth, Mary K., Ball, Melanie, and Coglaiti, Michaela Cimini February 2012.: RTI International Final Report - Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products, Table 3-11 on p. 3-17.

³⁴ The February 2012 report estimates that 490 establishments produce products that are both mechanically tenderized and containing added solutions.

³⁵ Based on slaughter volumes multiplied by average carcass weights in the Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Meat and Poultry Products, RTI International, February 2012.

³⁶ Ibid. Table 3-8 Proportions of Mechanically Tenderized-only Beef Product pounds by Packaging and labeling Type on p. 3-13, and Table 3-14 Estimated Pounds of Mechanically Tenderized-only Beef Products by Packaging and Labeling Type (Millions), p. 3-18.

number of retail establishments that would be involved with repackaging raw or partially cooked mechanically tenderized beef products or the number of labels they would require to be in compliance with this rule.³⁷ FSIS expects that very few retail facilities are producing mechanically tenderized beef. FSIS requests data on the number and size distribution of retail establishments that could be possibly affected by this proposed rule.

The proposed new descriptive designation requirement would apply to all raw or partially cooked needle- or blade-tenderized beef products going to retail stores, restaurants, hotels, or similar institutions, or other official establishments for further processing, unless such product is destined to be fully cooked at an official establishment. The proposed requirements for validated cooking instructions would apply to raw or partially cooked mechanically tenderized products destined for household consumers, hotels, restaurants, or similar institutions. If a second establishment repackages the product for household consumers, hotels, restaurants, or similar institutions, the second establishment would also be responsible for applying the validated cooking instructions to the product label. If retail stores repackage the product, they would have

³⁷ FSIS believes that the number of retailers involved in repackaging mechanically tenderized beef is small and declining, with large retailers and warehouse clubs moving toward ordering case-ready packaged beef products.

to include the descriptive designation and validated cooking instructions from the official establishment on the retail label.

This rule would affect foreign establishments that manufacture and export to the United States raw or partially cooked beef products that are mechanically tenderized, because foreign establishments that manufacture and export these products to the United States will be required to follow these same labeling requirements. FSIS requests information on the number of foreign establishments that would be affected if this proposed rule is finalized.

Expected Cost of the Proposed Rule

The proposed rule would require all official establishments that produce raw mechanically tenderized beef products to modify their product labels to include the term "mechanically tenderized" as part of the products' descriptive name and to add validated cooking instructions to the labels of all raw and partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions. To incorporate this information, establishments may add the required information to existing label designs with minor changes. As discussed below, establishments' and stores' costs likely would be mitigated

because the uniform compliance date may result in a number of labeling rules going into effect at the same time. Therefore, the establishments will have additional time to comply based on the delayed effective date provided by the uniform compliance labeling rule and will be able to limit label supplies based on the day that the labels will need to be modified. In addition, the uniform compliance date allows establishments time to use existing labels and will, therefore, result in minimal loss of inventory of labels.

Cost Analysis

On the basis of data provided by the FSIS Labeling and Program Delivery Staff, the Agency estimates that there are approximately 270,000 meat and poultry labels in the marketplace.³⁸ Of those, FSIS estimates that 50 percent of the total labels, or 135,000, are unique labels for raw meat and poultry products labeled at official establishments. This estimate of 135,000 may be an overestimate because it assumes an exclusive label for each variation of a product. Of the 135,000 labels, FSIS assumes that 23.8 percent,³⁹ or 32,130 labels, are

³⁸ In the proposed rule for Prior Label Approval System: Generic Label Approval (Docket FSIS-2005-0016), FSIS estimated that there were approximately 266,061 approved meat and poultry product labels in the marketplace. For the purpose of this analysis, FSIS chose to round the number of approved meat and poultry product labels in the marketplace to 270,000.

³⁹ From Muth, Mary K., Ball, Mary K., and Coglaiti, Michaela Cimini February 2012.: RTI International Final Report - Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products, p. 3-8.

for beef products. Using the 10.5-percent estimate for the share of beef products that are mechanically tenderized, and the 32,130 estimated number of beef labels, the estimated number of labels for mechanically tenderized beef products is 3,374. This proposed rule would require these products to add "mechanically tenderized" to their labels.

FSIS is developing a final rule that would require additional labeling of products with added solutions. If this proposed rule becomes final before the added solutions rule is in effect, then an additional 15.8 percent of all beef products, or 5,077 labels, would require the "mechanically tenderized" designation on their labels. (See proposed rule "Common or Usual Name Requirements for Meat and Poultry Products with Added Solutions" (76 FR 44855.) If both this rule on mechanically tenderized products and products with added solutions are in effect, establishments are likely to make all labeling changes at the same time.

The number of labels was not tracked by the FSIS Labeling Information System Database because many mechanically tenderized beef products are single ingredient products, and establishments may be eligible for generic approval of these labels. FSIS does not have data on partially cooked mechanically tenderized beef products but expects that the amount of these products is small and therefore has not included them in the cost calculations.

FSIS requests comments on the number of labels approved by establishments for raw and partially cooked mechanically tenderized beef products.

This cost analysis uses the mid-point label design modification costs for a minor coordinated label change, as provided in a March 2011 FDA report.⁴⁰ This report defines a minor change as one in which only one color is affected and the label does not need to be redesigned. We conclude that the labeling change that would be required by this proposed rule is a minor change because the words "mechanically tenderized" need to be added to the label, which is comparable to the addition of an ingredient to the ingredient list and the addition of validated cooking instructions is comparable to minimal changes to a facts panel (e.g. nutrition facts, supplement facts, or drug facts). For comparison purposes, in 2011, the Food and Drug Administration estimated that the required labeling costs for its final rule⁴¹ on the labeling of bronchodilators were deemed minor. The FDA required revisions to the ``Indications,`` ``Warnings,`` and ``Directions`` sections of the Drug Fact label. Using the RTI labeling model described in the March 2011 report, the FDA concluded that the revisions

⁴⁰ Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, FDA, March 2011. (Contract No. GS-10F-0097L, Task Order 5).

⁴¹ Labeling for Bronchodilators To Treat Asthma; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic 2011. Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 143

would be deemed minor. FSIS assumes that the addition of validated cooking instruction is similar to the aforementioned changes to the drug fact panel, and is therefore deemed minor. FSIS requests comments on these cost estimates.

FSIS expects that all label changes resulting from this proposed rule will be coordinated with planned label changes. The mid-point label design modification costs for a minor coordinated label change are an estimated \$310 per label. A coordinated label change is when a regulatory label change is coordinated with planned labeling changes by the firm. A coordinated change is likely because of uniform compliance labeling rules. These rules help affected establishments minimize the economic impact of labeling changes because affected establishments can incorporate multiple label redesigns required by multiple Federal rulemakings into one modification at 2-year intervals, to reduce the cost of complying with the final regulation.⁴² Moreover, this allows time to use existing labels and results in minimal losses of inventories of labels.

⁴² On December 14, 2004, FSIS issued a final rule that provided that the Agency will set uniform compliance dates for new meat and poultry product labeling regulations in 2-year increments and will periodically issue final rules announcing those dates. FSIS established January 1, 2016 as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2013, and December 31, 2014 (See 77 FR 76824). The final mechanically tenderized beef rule will likely be issued during this period. The March 2011 FDA report states that changes in labels for food products can be coordinated with firms' planned label changes within 42 months (see Table 3-1, Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, FDA, March 2011 (Contract No. GS-10F-0097L, Task Order 5)).

In the case of a coordinated label change, only administrative and recordkeeping costs are attributed to the regulation, and all other costs are not.⁴³ FSIS estimates the cost to be \$ 1.05 million (3,374 labels x \$310) for mechanically tenderized beef products only; such products do not contain added solution. The annualized cost to the industry for products that are mechanically tenderized only is estimated to be \$140 thousand at 7 percent for 10 years (\$120 thousand when annualized at 3 percent for 10 years).

FSIS is developing a final rule that would require additional labeling of products with added solutions. If this proposed rule becomes final before the added-solution rule is finalized, the cost estimated would be higher to reflect an additional 15.8 percent (or 5,077 labels) of all beef products that are both mechanically tenderized and containing added solutions. This would result in an additional one-time total cost (for all affected labels for mechanically tenderized beef containing added solutions) of \$1.57 million or \$209 thousand

⁴³ From the 2011 FDA labeling model paper, the costs of a label change (p. 3-3) include administrative and recordkeeping activities, graphic design, market testing (organizing focus groups), prepress (convert design to plates), engraving, printing, and disposing of old inventory. The regulatory costs of a coordinated label change are administrative and recordkeeping costs "associated with understanding the regulation, determining their responses, tracking the required change throughout the labeling change process, and reviewing and updating their records of product labels. The costs other than administrative and recordkeeping are not attributable to the regulation if the labeling change is coordinated with a planned change." (p. 3-5). Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, FDA, March 2011. (Contract No. GS-10F-0097L, Task Order 5).

when annualized at 7 percent for 10 years (\$179 thousand when annualized at 3 percent for 10 years).

This proposed rule would require validated cooking instructions on packages for beef that is only mechanically tenderized and beef that is both mechanically tenderized and contains added solutions. Establishments could also incur costs to validate the required cooking instructions for raw and partially cooked needle- or blade-tenderized beef products. These costs would be incurred to ensure that the cooking instructions are adequate to destroy any potential pathogens that may remain in the beef products after being tenderized. Most cooking instruction validations would be contracted out to universities or conducted by trade associations or large establishments. It is estimated that a validation study would cost between \$5,000 and \$10,000 per product line with one formulation. Most studies will validate cooking instructions for beef products with two formulations: injected with or without solution; therefore, the total cost per validation study would be between \$10,000-\$20,000.⁴⁴ Industry cost would likely be relatively small because FSIS is issuing guidance along with this NPRM that establishments can use to develop cooking instructions. FSIS is requesting comments on the number of cuts

⁴⁴ Per telephone conversation with the Grocery Manufacturers Association Director of Science Operations, Food Protection.

per establishment that would require validated cooking instructions and comment on whether establishments would use FSIS' guidance to develop the validated cooking instructions. In addition, FSIS requests comments on the estimated costs for developing validated cooking instructions. For purposes of this analysis, FSIS has assumed that the costs of developing validated cooking instructions would be minimal because FSIS assumes that most establishments will follow FSIS' guidance.

FSIS Budgetary Impact of the Proposed Rule

This proposed rule will result in no impact on the Agency's operational costs because the Agency will not need to add any staff or incur any non-labor expenditures since inspectors periodically perform tasks to verify the presence of mandatory label features and to ensure that the label is an accurate representation of the product. The Agency's cost to develop guidance material that establishments can use to develop cooking instructions will be minimal because such guidance exists and can be modified and posted on the FSIS Web site in fewer than six staff-hours.

FSIS is soliciting comments and data on any other potential federal costs that might result from finalizing this rule.

Expected Benefits and Miscellaneous Impacts of the Proposed Rule

The Agency has determined that the proposed new labeling requirements will improve public awareness of product identities. The proposed rule will clearly differentiate non-intact, mechanically tenderized beef products from intact products, thereby providing truthful and accurate labeling of beef products.

As stated earlier, when purchasing a beef product, tenderness is a key factor. However, not all needle- or blade-tenderized beef products are readily distinguished from non-tenderized beef products. Therefore, by requiring the descriptive designation "mechanically tenderized" on the labels of this product, the consumers will be informed of the additional attributes of the product when deciding whether to purchase the product. Although the benefits of having such additional information cannot be quantified, providing better market information to consumers could promote better competition among establishments that produce beef products. In addition, if the new label causes a divergence in price between intact and mechanically-tenderized beef, there would be a number of changes in consumer and producer surplus. Consumers who purchase mechanically-tenderized beef in the absence of the rule and would continue doing so in its presence would gain surplus due to the decrease in price for mechanically-tenderized beef, while consumers purchasing intact beef in the absence of the rule

would experience a loss of surplus due to the increase in price for intact beef. Some producers of intact beef or other meats would realize a surplus increase because consumers may substitute such products for mechanically tenderized beef.

FSIS has concluded that labeling information on needle- or blade-tenderized beef products may help consumers and retail establishments better understand the product they are purchasing. This knowledge is the first step in helping consumers and retail establishments become aware that they need to cook these products differently than intact beef products before the products can be safely consumed. Additionally, by including cooking instructions, the food service industry and household consumers will be made aware that a mechanically tenderized beef product or injected beef product needs to be cooked to a minimum internal temperature and may need to be maintained at this temperature for a specific period of time to sufficiently reduce the presence of potential pathogens in the interior of the beef product.

FSIS generated an estimate of the annual number of illnesses from mechanically (needle- or blade-) tenderized beef steaks and roasts and mechanically tenderized beef steaks and roasts that contain added solutions that could potentially be avoided as a result of this proposed rule. FSIS evaluated the effect of additional cooking of non-intact product by first

determining the implied concentration of organisms prior to cooking given current information, then determining the effect of adding additional cooking. Additional cooking is modeled to a minimum temperature of 160⁰ F. Current cooking practices as captured in the EcoSure dataset do not specifically include the time from when the final cooking temperature was recorded to when consumption occurred. It is likely that product in this data set encountered a range of dwell times. FSIS recommends in its guidance concerning steaks and roasts a cooking temperature of 145⁰ F with 3 minutes resting time for cooking steaks and whole roasts because data support that this would be equivalent to cooking at 160⁰ F without holding a product at that temperature for any dwell time.⁴⁵ FSIS' guidance concerning cooking steaks and whole roasts is located at <http://blogs.usda.gov/2011/05/25/cooking-meat-check-the-new-recommended-temperatures/>. If consumers adopt such practices, results would be comparable to consumers cooking product to 160⁰ F but not holding product at that temperature for any dwell time.⁴⁶ Therefore, FSIS used the results from the risk analysis

⁴⁶ Equivalency in cooking temperatures and times can be estimated using D and Z-values. The D-value is a measure of how long bacteria must be exposed to a particular temperature to effect a 1 log₁₀ reduction. The Z-value is a measure of how much temperature change is necessary to effect a 1 log₁₀ change in the D-value. Although these values have not been measured for *E. coli* O157:H7 in steaks, they have been measured in ground beef. At 158°F (70°C) *E. coli* O157:H7 had a D-value of about 3.3 seconds, at 144.5°F (62.5°C) the D-value was 52.8 seconds. (Murphy, R. Y., E. M. Martin, et al.

that estimate the benefits of consumers cooking mechanically tenderized product to 160° F without a dwell time because they are equivalent to 145° F with 3 minutes of dwell time and because the Agency did not have information about dwell time from the risk analysis.

The Centers for Disease Control and Prevention (CDC) recently completed an analysis attributing foodborne illnesses to their sources. Painter, et al., examined outbreak data from 1998 through 2008 and identified 186 outbreaks of *E. coli* O157 resulting in 4,844 illnesses during that period.⁴⁷ As a consequence of this analysis, Painter, et al., attributed 39.4% of illnesses or 1,909 (4,844 x 0.394) to beef.

Of the 6 outbreaks in tenderized products described in Table 2, 5 occurred during the time frame analyzed by Painter, et al. These 5 outbreaks (occurring between 2000 and 2007) resulted in 151 illnesses. Thus, approximately 7.9% (151/1,909)

(2004). "Thermal process validation for *Escherichia coli* O157:H7, *Salmonella*, and *Listeria monocytogenes* in ground turkey and beef products." *J Food Prot* **67**(7): 1394-1402.) Three minutes at 145°F would be equivalent to more than 10 seconds at 160°F. Using the Z-value for *E. coli* O157:H7 in ground beef yields similar estimates. The Z-value was given as 9.8°F (5.43°C). Changing the temperature from 160°F to 145°F would then represent an increase in D-value of about 1.5 log10. Thus, 3 minutes at 145°F would be equivalent to 5.7 seconds at 160°F. In either case, three minutes at 145°F is more than equivalent to an instantaneous temperature (< 1 sec) at 160°F.

⁴⁷Painter, J., R. Hoekstra, et al. (2013). "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998-2008." *Emerg Infect Dis* 9(3): 407-415.

of *E. coli* O157 illnesses are attributable to tenderized beef product.

Painter et al.'s work includes the illnesses associated with outbreaks, which constitute only a fraction of the overall *E. coli* O157 illnesses that occur each year. For an estimate of overall illness numbers, we turn to another CDC study, whose authors estimate that there are 63,153 annual illnesses due to *E. coli* O157 in the United States from all sources.⁴⁸ To determine the annual number of illnesses from *E. coli* O157 (STEC O157), CDC begins with the annual incidence of STEC O157 infections reported to CDC's Foodborne Diseases Active Surveillance Network (FoodNet) sites from 2005 to 2008. This value is adjusted up using an under-diagnosis multiplier that is based on the following factors:

1. Whether a person with diarrhea seeks medical care. CDC bases this on unpublished surveys of persons with bloody or non-bloody diarrhea conducted in 2000-2001, 2002-2003, and 2006-2007. CDC estimates that about 35% of persons with bloody diarrhea (about 90% of STEC O157 illnesses) would seek medical care and about 18% of persons with non-bloody diarrhea would seek medical care.

⁴⁸ Scallan, E., R. M. Hoekstra, et al. (2011). "Foodborne illness acquired in the United States--major pathogens." Emerg Infect Dis **17**(1): 7-15.

2. Whether a person seeking medical care submits a stool specimen. This is also based on unpublished surveys of persons with bloody or non-bloody diarrhea conducted in 2000-2001, 2002-2003, and 2006-2007. CDC estimates that about 36% of persons with bloody diarrhea seeking medical care and about 19% of persons with non-bloody diarrhea seeking medical care would submit stool specimens.

3. Whether a laboratory receiving a stool specimen would routinely test it for STEC O157. This is based on a published study from the FoodNet Laboratory Survey.⁴⁹ CDC estimates that 58% of laboratories would routinely test for O157 STEC.

4. How sensitive the testing procedure is. CDC used a laboratory test sensitivity rate of 70% based on studies of *Salmonella*.^{50, 51}

5. CDC also adjusted for geographical coverage of the FoodNet sites and for the changing United States population for the years 2005-2008.

The value was also adjusted down for the following factors:

⁴⁹ Voetsch, A. C., F. J. Angulo, et al. (2004). "Laboratory practices for stool-specimen culture for bacterial pathogens, including *Escherichia coli* O157:H7, in the FoodNet sites, 1995-2000." Clin Infect Dis 38 Suppl 3: S190-197.

⁵⁰ Chalker, R. B. and M. J. Blaser (1988). "A review of human salmonellosis: III. Magnitude of *Salmonella* infection in the United States." Rev Infect Dis 10(1): 111-124.

⁵¹ Voetsch, A. C., T. J. Van Gilder, et al. (2004). "FoodNet estimate of the burden of illness caused by nontyphoidal *Salmonella* infections in the United States." Clin Infect Dis 38 Suppl 3: S127-134.

1. The proportion of illnesses that were acquired outside of the United States. Based on the proportion of FoodNet cases of STEC O157 infection who reported travel outside the United States within 7 days of illness onset (2005-2008), CDC estimated that 96.5% of illnesses were domestically acquired.

2. The proportion of STEC O157 outbreak-associated illnesses that was due to foodborne transmission. Based on reported outbreaks CDC estimated that 68% were foodborne.⁵² The overall effect of the upward and downward adjustments is a multiplier of 26.1 that is applied to the reported number of illness which is then adjusted down by about 35% to account for domestically acquired foodborne illness.

CDC's credible interval surrounding this point estimate ranges from 17,587 to 149,631.⁵³ The estimated annual illnesses due to mechanically tenderized product is given by 63,153 (annual estimated illnesses of *E. coli* O157:H7⁵⁴) x 0.394 (proportion of *E. coli* O157:H7 illnesses attributable to beef⁵⁵) x 0.079 (proportion of beef attributable illnesses due to

⁵² Rangel, J. M., P. H. Sparling, et al. (2005). "Epidemiology of *Escherichia coli* O157:H7 outbreaks, United States, 1982-2002." *Emerg Infect Dis* 11(4): 603-609.

⁵³ Scallan, E., R. M. Hoekstra, et al. (2011). "Foodborne illness acquired in the United States--major pathogens." *Emerg Infect Dis* 17(1): 7-15.

⁵⁴ Ibid.

⁵⁵ Painter, J., R. Hoekstra, et al. (2013). "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998-2008." *Emerg Infect Dis* 9(3): 407-415.

tenderized product⁵⁶) = 1,965. This gives a range of estimated annual illnesses from 547 ($= 17,587 \times 0.394 \times 0.079$) to 4,657 ($= 149,631 \times 0.394 \times 0.079$). FSIS requests comments on the methods used, including the application of the underlying datasets, to estimate illnesses attributable to mechanically tenderized beef and alternative methods for making this estimate. Because, combining three sources of information introduces uncertainty around the precision of these estimates, we are particularly interested in approaches to quantifying the uncertainty inherent in the method used.

An analysis of the NHANES 2005–2006 Dietary Interview, Individual Foods, First Day, and Second Day files estimated approximately 11.7 billion servings annually of steaks and roasts. FSIS contracted with Research Triangle Institute to estimate market shares for mechanically tenderized beef and mechanically tenderized beef with added solutions.⁵⁷ After accounting for the proportion of all beef that was ground, FSIS estimated that 21.0% of non-ground product was mechanically tenderized only and that 31.6% of non-ground product was mechanically tenderized with added solutions. Thus, FSIS

⁵⁶ 151 outbreak illnesses attributable to tenderized beef out of 1,909 outbreak illnesses attributable to all beef ($151 / 1,909 = 0.079$).

⁵⁷ Muth, M. K., M. Ball, et al. (2012). Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products. Research Triangle Park, NC 27709, RTI International, 3040 Cornwallis Road.

estimates that mechanically tenderized beef accounts for 6.2 billion servings annually. FSIS also estimates that the frequency of illness for mechanically tenderized product is 1,965 / 6.2 billion or 320 illnesses per billion servings, with a range from 88 (= 547 / 6.2 billion) to 751 (= 4,657 / 6.2 billion) illnesses per billion servings.

The dose response function for a pathogen associates an average dose with a corresponding frequency of illness. For *E. coli* O157:H7 the dose response function is characterized by a linear part in which the predicted probability of illness per serving across all exposures is proportional with respect to an average dose and by a non-linear part in which the predicted probability of illness is not proportional.

In the case of *E. coli* O157 illnesses attributable to mechanically tenderized beef, the frequency of illness is very low; therefore the mean dose across the population of servings that could account for this frequency of illness is also low. For one set of parameters the dose response function for *E. coli* O157:H7 corresponds to an average dose of 0.0001 *E. coli* O157:H7 bacteria per serving with a frequency of illness of 320 per billion.⁵⁸ This average dose is more than 5 log₁₀ below the point at which the dose response function becomes non-linear.

⁵⁸ Powell, M., E. Ebel, et al. (2001). "Considering uncertainty in comparing the burden of illness due to foodborne microbial pathogens." Int J Food Microbiol 69(3): 209-215.

This makes the average dose an appropriate surrogate for the distribution of all doses.⁵⁹ At the lower end of the range of illnesses, a dose of 0.000028 *E. coli* O157:H7 bacteria per serving corresponds to a frequency of illness of 88 per billion servings. At the upper end of the range of illnesses, a dose of 0.00024 *E. coli* O157:H7 bacteria per serving corresponds to a frequency of illness of 751 per billion servings. Both of these values also fall well below the point at which the dose response function becomes non-linear.

From a post-cooking dose of 0.0001, a pre-cooking dose of *E. coli* O157:H7 bacteria can be calculated by determining the average contamination level needed to survive cooking. The 2007 EcoSure consumer cooking temperature audit⁶⁰ involved the collection of data from primary shoppers of over 900 households geographically dispersed across the country. Participants were asked to record the final cooking temperature and name or main ingredient of any entrée they prepared during the week of the study. Of the 3,257 recorded consumer cooking temperatures in the database for all products, 318 recorded consumer cooking temperatures ranging from 82°F to 212°F for beef (not ground).

⁵⁹ Williams, M. S., E. D. Ebel, et al. (2011). "Methodology for determining the appropriateness of a linear dose-response function." *Risk Anal* 31(3): 345-350.

⁶⁰ EcoSure-EcoLab. (2007). "EcoSure 2007 Cold Temperature Database." FoodRisk.org Retrieved May 26, 2010, from <http://foodrisk.org/exclusives/EcoSure/>.

Table 3 shows the number of observations for each recorded cooking temperature.

Table 3: Final recorded consumer cooking temperatures for beef (not ground) in 2007 EcoSure consumer cooking temperature audit (EcoSure-EcoLab, 2007).

Final cooking temperature	Observations	Percent
80-89	1	0.3%
90-99	3	0.9%
100-109	6	1.9%
110-119	11	3.5%
120-129	19	6.0%
130-139	27	8.5%
140-149	38	11.9%
150-159	54	17.0%
160-169	61	19.2%
170-179	31	9.7%
180-189	45	14.2%
190-199	14	4.4%
200-209	7	2.2%
210-219	1	0.3%

Sixty seven (21%) of the recorded cooking temperatures were below 140°F and 159 (50%) of the temperatures were below 160°F. A 2010 USDA Agricultural Research Service (ARS) study by Luchansky et al.,⁶¹ looked at the relationship between final cooking temperatures and log₁₀ reductions for mechanically tenderized beef. An additional ARS study by Luchansky, et al.,⁶² also examined the relationship between final cooking

⁶¹ Luchansky, J. B., A. C. Porto-Fett, et al. (2012). "Fate of Shiga toxin-producing O157:H7 and non-O157:H7 *Escherichia coli* cells within blade-tenderized beef steaks after cooking on a commercial open-flame gas grill." J Food Prot **75**(1): 62-70.

⁶² Ibid.

temperatures and \log_{10} reductions for chemically injected beef (mechanically tenderized beef with added solutions). Equations derived from these studies combined with the distribution of final cooking temperatures shown in Table 3 estimate that an average pre-cooking dose of 0.0188 *E. coli* O157:H7 bacteria per serving would result in an average post-cooking dose of 0.0001. Thus, a pre-cooking dose of 0.0188 corresponds with the estimate of 1,965 illnesses. Given the current cooking distribution, more than 98% of the 1,965 illnesses are attributed to cooking temperatures below 160°F and less than 1% to cooking temperatures equal to or greater than 160°F.

To evaluate the effect of using a higher minimum cooking temperature, FSIS modified the distribution derived from the EcoSure (2007) data set so that all of the observations that were originally below 160°F were set to 160°F. FSIS then calculated a new predicted number of illnesses using this modified cooking temperature distribution with the pre-cooking dose of 0.0188. This changes the post-cooking average dose from 0.0001 *E. coli* O157:H7 bacteria per serving to an average dose of 0.0000039, which corresponds to a frequency of illness of 13 per billion. With this change, the predicted number of illnesses decreases from 1,965 to 78. Thus, if all consumers cook all mechanically tenderized beef to at least 160°F, the resulting total number of illness will be 78. Analogous

calculations yield illness estimates of 22 and 184 illness, respectively, if the baseline annual illness totals are 547 and 4,657.

The annual estimated number of illness averted or prevented is estimated at 1,887 (1,965 illness less 78 illness), with a range of 525 illness (547 illness - 22 illness) to 4,473 illnesses (4,657 illness- 184 illness), if mechanically tenderized and mechanically tenderized beef containing added solution is cooked to a minimum temperature of 160°F (which is equivalent to cooking to a minimum internal temperature of 145°F with 3 minutes of dwell time). However, FSIS knows that not all consumers or food service providers will change their behavior based on reading the labels and, therefore, the Agency has estimated the uncertainty surrounding the number of illnesses that will be averted by obtaining ranges for both the consumer and food service provider response rate, as well as using the range for the estimated number of illnesses if all consumers and food service providers cooked the product at a minimum recommended temperature.

To determine this, FSIS used studies on the impacts of food product labels on consumer behavior. These studies estimated the proportion of consumers changing their behavior in response to the presence of cooking instructions (safe handling

instructions) ranging from 15 to 19 percent.⁶³ In a study of the nutrition fact panel on food products, the American Dietetic Association (ADA) conducted a survey which indicated that 56 percent of the people interviewed claimed to have modified their food choices after using this nutrition fact labeling (American Dietetic Association, 1995).⁶⁴ Finally, the Food Marketing Institute (FMI) in early 1995 indicated that the nutrition fact label may be causing some dietary change. Fifteen percent of the shoppers indicated that they had stopped buying products they had regularly purchased, after reading the label.⁶⁵ We use the range (15 to 56 percent) as the estimate for the impact of labels on consumer behavior in retail, with our primary estimate equaling the average of available estimates, or 24 percent. FSIS requests comments on the percentage of consumers who would change their behavior after reading the labels.

⁶³ Yang states that 15% (51% of respondents seen the Safe Handling Instruction labels x 79% remembered reading the labels x 37% changing their behavior after seeing and reading the labels), and Bruhn states that 17% (60% of respondents seen the labels x 65% said that their awareness was increased x 43% said that they changed their behavior). Ralston states that 19% (67% of respondents seen the label x 29% who changed their behavior).

⁶⁴ America's Eating Habits: Changes and Consequences. U.S. Department of Agriculture, Economic Research Service, Food and Rural Economics Division. Agriculture Information Bulletin No. 750

⁶⁵ Food Marketing Institute (FMI) states that of the 43 percent of the shoppers interviewed, who had seen the label, 22 percent indicated it had caused them to start buying and using food products they had not used before, and 34 percent said they had stopped buying products they had regularly. We use the higher percentage of 15% (43% x 34%) in our estimate. FMI and Prevention Magazine Report Shopping for Health: Balancing, Convenience, Nutrition and Taste, 1997

In addition, the RTI study indicates that the food service industry market share for mechanically tenderized beef and beef containing added solution is estimated at 53 percent and the market share for retail for the same products is estimated at 47 percent.⁶⁶ In the absence of data, FSIS assumes for its primary estimate that the rule-induced percentage reduction in illness will be the same for food service establishments as for mechanically-tenderized beef purchased at retail (24 percent), and presents a range in which between 0% and 100% of food service providers will follow the validated cooking instructions. Should the rule become final, food service providers will be able to identify mechanically tenderized beef product as such and will therefore be able to follow the Food Code cooking instructions. The Food Code (developed by the Conference for Food Protection and adopted by 49 states, which represent 96 percent of the population) recommends cooking mechanically tenderized and injected meats to a minimum temperature of 145°F for a minimum of 3 minutes. The Food Code, however, states that retail service facilities may serve such product rare if they notify consumers of the risk.⁶⁷ Therefore, FSIS assumes that at a minimum, zero food service providers will

⁶⁶ RTI, pp. 3-12 and 3-14

⁶⁷ In the U.S. Department of Health and Human Services, Public Health Service, FDA Food Code, 2009, S3-411.11 (D), a rare animal food such as rare meat other than whole-muscle, intact steaks, may be served or offered for sale upon consumer request or selection in a ready-to-eat form if the consumer is informed that to ensure its safety, the food is to be more fully cooked.

follow the cooking instructions. FSIS is including the lower end to recognize that some food service providers may recognize customers' requests that the meat be cooked rare. FSIS is requesting comments on food service providers' likely response to new labeling of mechanically-tenderized beef, including any cost that would be incurred by such establishments as a result of changing standard operating procedures related to intact and mechanically-tenderized beef.

Table 4 shows the estimated reduction in illness numbers based on these assumptions for consumer and food service provider behavior. To derive the estimated number of illnesses averted and focusing first on inputs derived from Scallan et al.'s primary estimate, the range for the estimate would be 133 illness (1,887 illnesses (mid-point estimate from the risk analysis) *47% (retail share of mechanically tenderized beef market) * 15% (lower end of the range for percent of consumer using validated cooking instructions) + 53% (food service share of mechanically tenderized beef)* 0% (lower end of the range for food service compliance with validated cooking instructions)) to 1,497 illness averted (1,887 illnesses (mid-point estimate from the risk analysis) * 47% (retail share of mechanically tenderized beef market) *56% (upper end of the range for percent of consumers using validated cooking instructions) + 53% (food service share of mechanically tenderized beef) * 100% (upper end

of the range for food service compliance with validated cooking instructions)). The primary estimate is 460 illnesses.

Table 4: Response Rate and Resulting Averted Illnesses

Category	Retail	Food Service	Total	Averted Illnesses	Expected Benefits
Share of Mechanically Tenderized Beef in Retail vs. Food Service	47%	53%	100%		
Response to Label	15 to 56% ¹	0% to 100%	7% to 79%	133 to 1,497	\$436,000 to \$4,911,000
Primary ²	24% ¹	24% ¹	24%	460	\$1,511,000
Lower Bound ³			24% (7% to 79%)	128 (37 to 416)	\$420,000 (\$121,000 to \$1,366,000)
Upper Bound ⁴			24% (7% to 79%)	1,091 (315 to 3,548)	\$3,581,000 (\$1,035,000 to \$11,641,000)

¹ The average of the percentages of consumer response rate: Yang 15%, Bruhn 17%, Ralston 19%, American Dietetic Association 56%, and FMI 15% as discussed in the benefits section.

²Using estimated mechanically tenderized beef preventable illnesses of 1,887 illnesses.

³Using estimated mechanically tenderized beef preventable illnesses of 128 illnesses.

⁴Using estimated mechanically tenderized beef preventable illnesses of 1,091 illnesses.

With the primary estimate, 24% of all mechanically tenderized beef previously cooked to a lower temperature is cooked to the suggested temperature, which is equivalent to 460 illnesses averted or prevented.

Using the FSIS estimate for the average cost per case for an *E. coli* O157:H7 illness of \$3,281,⁶⁸ expected benefits from

⁶⁸ The FSIS estimate for the cost of *E. coli* O157:H7 (\$3,281 per case, - 2010 dollars) was developed using the USDA, ERS Foodborne Illness Cost Calculator: STEC O157 (June 2011). FSIS updated the ERS calculator to incorporate the Scallan (2011) case distribution for STEC O157. Scallan E. Hoekstra, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et. al. 2011 January.

this proposed rule are \$1,511,000 per year (with a range of \$436,000 to \$4,911,000). Using the credible interval from Scallan et. al provides expected benefits of \$420,000 per year for 128 illnesses prevented (with a range of \$121,000 to \$1,366,000) for the lower bound of the credible interval and expected benefits of \$3,581,000 per year for 1,091 illnesses prevented (with a range of \$1,035,000 to \$11,641,000) in the upper bound of the credible interval. This estimate for the average cost of an *E. coli* O157:H7 illness is derived by using the current version of ERS Cost calculator (for *E. coli*) and replacing the case numbers with new case numbers based on Scallan's report.

For *E. coli*, FSIS adjusted Scallan's case distribution to fit the ERS Cost Calculator because Scallan reported each illnesses in three categories (doctor visits, hospitalization, and death) while the ERS Cost Calculator for *E. coli* O157 has seven severity categories. By changing only the case numbers, FSIS kept all other assumptions in the ERS Cost Calculator. ERS has recently updated the dollar units to 2010 dollars and FSIS is using these estimates.

These estimates represent a minimal estimate for an average cost of illness because they only include medical costs and

"Foodborne Illness Acquired in the United States—Major Pathogens". Emerging Infectious Diseases.

loss-of-productivity costs. They do not include pain and suffering costs.

FSIS believes that consumers prefer lower cooking temperatures⁶⁹ and therefore they may substitute other meat choices rather than cooking at a higher recommended temperature included in cooking instructions. This welfare loss associated with substituting to less-preferred meats or cooking to temperatures that are higher than ideal (from a taste perspective) was not quantified in the analysis.

Conclusion

The cost to produce labels for mechanically tenderized beef is a one-time cost of \$1.05 million or \$2.62 million if this rule is in effect before the added solutions rule. The annualized cost is \$140,000 for 10 years at a 7 percent discount rate or \$349,000 over 10 years at a 7 percent discount rate if this rule is in effect before the added solutions rule.

The expected number of illnesses prevented would be 460 per year, with a range of 133 to 1,497, if the predicted percentages of beef steaks and roasts are cooked to an internal temperature of 160° F (or 145° F and 3 minutes of dwell time). These prevented illnesses amount to \$1,511,000 per year in benefits with a range of \$436,000 to \$4,911,000. The expected annualized

net benefits are \$296,000 to \$4,771,000 with a primary estimate of \$1,371,000.

If, however, this rule is in effect before the added solutions rule, the expected annualized net benefits are then \$1,162,000, with a range of \$87,000 to \$4,562,000.

Using the lower end of the credible interval from Scallan et. al provides an expected number of illness prevented of 128 per year, with a range of 37 to 416, as discussed earlier. These prevented illnesses amount to \$420,000 in benefits, with a range of \$121,000 to \$1,366,000. The expected annualized net benefits for the lower end of the Scallan's credible interval are \$280,000, with a range of -\$19,000 to \$1,226,000, if this rule goes into effect before the added solutions rule.

Using the upper end of the credible interval from Scallan et. al provides an expected number of illness prevented of 1,091 per year, with a range of 315 to 3,548 as discussed earlier. These prevented illnesses amount to \$3,581,000 in benefits, with a range of \$1,035,000 to \$11,641,000. The expected annualized net benefits for the upper end of the Scallan's credible interval are \$3,441,000, with a range of \$895,000 to \$11,501,000, if this rule goes into effect after the added solutions rule,

In addition to the quantified net benefits mentioned above, the rule would generate the unquantifiable benefits of increased

consumer information and market efficiency, an unquantified consumer surplus loss and an unquantified cost associated with food service establishments changing their standard operating procedures.

As mentioned above, FSIS is using an estimate of the number of establishments producing needle- or blade-tenderized beef products and the number of labels that would need to be modified as a result of this proposed rule. FSIS requests comments on the number of official and retail establishments that are producing or packaging mechanically tenderized beef products and the number of labels that they might need to modify should this proposal be finalized.

Additionally, FSIS cannot estimate the number of validation studies that would be necessary to develop cooking instructions for raw and partially cooked needle- or blade-tenderized beef products. In addition, FSIS requests comments on the costs of conducting these validation studies.

Alternatives

Vacuum-Tumbled Beef Products

Some beef products are vacuum-tumbled to marinate and tenderize the product. The vacuum increases absorption of the marinade, while tumbling both tenderizes the product and increases absorption of the marinade. Vacuum-tumbled beef is a non-intact product, though its appearance is similar to whole,

intact product. Research shows that the process of vacuum tumbling a product increases bacterial migration into the interior of the product.^{70,71} However, FSIS does not have sufficient data to understand the magnitude of the risk of pathogens that may be introduced into product as a result of vacuum tumbling. Therefore, the Agency is requesting that the public submit data concerning the safety of vacuumed tumbled beef products. In addition, FSIS is asking for comments to see whether vacuum tumbled beef product should be considered mechanically tenderized product and thus subject to the provisions of this proposed rule if it becomes final.

Enzyme-Formed Product

Some meat and poultry products are formed with transglutaminase enzyme (TG enzyme). TG enzyme is approved for use as a cross-linking binder to form product, e.g., through binding pieces of beef tenderloin together to form a larger beef tenderloin steak or roast. FSIS regulations (9 CFR 317.8(b)(39) and 381.129(e)) require labeling for meat and poultry products that are formed or re-formed with TG enzyme as a binder as part of the product name, e.g., "Formed Turkey Thigh Roast." Formed

⁷⁰ Warsaw, CR, Orta-Ramirez A, Marks BP, Ryser ET, Booren AM. 2008. Single directional migration of Salmonella into marinated whole muscle turkey breast. *Journal of Food Protection*. 71(1):13-156.

⁷¹ Warsow, C.R., Marks, B.P., Ryser, E.T., Orta-Ramirez, A., Booren, A.M., Effects of vacuum tumbling on Salmonella migration into the interior of intact, marinated turkey breasts.
http://ift.confex.com/ift/2003/techprogram/paper_19598.htm.

products are non-intact. However, the formed products are already labeled in a manner that distinguishes them from other products. FSIS requests comment on whether this labeling is sufficient to inform consumers of the nature of formed product and on whether any final rulemaking should include additional labeling requirements, such as validated cooking instructions on any not-ready-to-eat formed product. FSIS requests data on the volume of formed product, the volume of formed product sold at retail stores versus food service facilities, and any available data on whether consumers typically cook formed product at time and temperature combinations sufficient to destroy pathogens.

FSIS considered several alternatives to the proposed rule:

Option 1. Extend labeling requirements to include vacuum tumbled beef products and enzyme-formed beef products. FSIS considered the option of proposing to amend the labeling regulations to include a new requirement for labeling all vacuum tumbled and enzyme-formed beef products. But, as discussed earlier, FSIS does not have sufficient data concerning the production practices and risks of consuming vacuum tumbled beef products and enzyme-formed beef products to proceed with this option. FSIS is requesting comments and data on these products.

Option 2. Extend the proposed labeling requirements to all needle- or blade-tenderized meat and poultry products. FSIS

considered the option of proposing to amend the labeling regulations to include a new requirement for labeling all mechanically tenderized meat and poultry products. However, as discussed above, FSIS does not have sufficient data concerning the production practices and risks of consuming mechanically tenderized poultry products or mechanically tenderized meat products, other than beef, to proceed with this option.

Option 3. Validated cooking instructions for needle or blade-tenderized beef, needle-injected beef, and all beef containing solutions. FSIS considered the option of proposing to amend the labeling regulations to require validated cooking instructions for needle or blade tenderized beef, needle-injected, and all beef containing solutions. However, FSIS did not find any outbreak data for products that contain added solutions but are not injected. In addition, if products are marinated but not injected, the pathogen remains on the surface of the product and would typically be eliminated, even if the product is cooked to rare temperatures. Therefore, FSIS does not have any data necessary to substantiate the need for this alternative.

Regulatory Flexibility Analysis

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). This determination was made because the rule will affect the labeling of about 10.5% of 24.3 billion pounds of beef products. Over 97 percent of the 555 federal establishments that produce mechanically tenderized beef products could possibly be affected by this proposed rule are small or very small according to the FSIS HACCP definition. There are about 251 very small establishments (with fewer than 10 employees) and 291 small establishments (with more than 10 but less than 500 employees). Therefore, a total of 542 small and very small establishments could possibly be affected by this rule. The FSIS HACCP definition assigns a size based on the total number of employees in each official establishment. The Small Business Administration definition of a small business applies to a firm's parent company and all affiliates as a single entity.

These small and very small manufacturers, like the large manufacturers, would incur the costs associated with modifying product labels to add on the labels "mechanically tenderized"

and validated cooking instructions needed to ensure adequate pathogen destruction.

Based on the estimated number of labels that will be required by the establishments, the cost will add an average of \$0.001 per package (\$1.05 million/951 million packages of needle- or blade-tenderized beef).⁷² The average cost per establishment would be \$1,884 per establishment (\$1.05 million/555). Also, small and very small establishments will tend to have a smaller number of unique products and will therefore have a smaller number of labels to modify, and therefore less labeling cost.

The labeling costs discussed above are one-time costs. FSIS believes these one-time costs will not be a financial burden on small entities.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.), the information collection requirement included in this proposed rule has been submitted for approval to OMB.

Title: Mechanically Tenderized Beef Products

Type of Collection: New

⁷² FSIS estimates that the annual quantity of mechanically tenderized beef at is about 951 million packages ((2.6 billion pounds of mechanical tenderized beef produced/2.735 average weight of a retail package according to the National Cattlemen's Beef Association).

Abstract: FSIS is proposing to require the use of the descriptive designation "mechanically tenderized" on the labels of needle- or blade-tenderized beef products, including beef products injected with marinade or solution, that do not fall under a regulatory standard of identity. FSIS is also proposing that the print for all words in the descriptive designation appear as the product name in the same style, color, and size and on a single-color contrasting background. In addition, FSIS is proposing to require that labels of raw and partially cooked needle- or blade-tenderized beef products include validated cooking instructions that inform consumers that these products need to be cooked to a specified minimum internal temperature and whether they need to be held at that minimum temperature or higher for a specified time before consumption, i.e., dwell time or rest time, to ensure that they are fully cooked.

The average burden per response and the annual burden hours are explained below and summarized in the charts which follow.

Estimated Annual Burden: Mechanically Tenderized Beef Products

Recordkeeping:

Estimated Annual Recordkeeping Burden for Mechanically
Tenderized Beef Products

Respondents: Official meat establishments.

Estimated Number of Respondents: 555.

Estimated Number of Responses per Respondent: 30.454.

Estimated Total Annual Responses: 16,902.

Estimated Total Annual Recordkeeping Burden: 985.95 hours.

	Estimated No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Responses in Minutes	Total Annual Burden Hours
Establishments maintain labels on file	555	15.227	8,451	2	281.7
Establishments maintain validated cooking instructions on file	555	15.227	8,451	5	704.25
Total Recordkeeping Burden	555	30.454	16,902	7	985.95

Reporting:

Estimated Annual Reporting Burden for Mechanically Tenderized

Beef Products

Respondents for this Proposed Rule: Official meat establishments.

Estimated Number of Respondents: 555.

Estimated Number of Responses per Respondent: 30.454.

Estimated Total Annual Responses: 16,902.

Estimated Total Annual Reporting Burden on Respondents:
18,733.05 hours.

	Estimated Number of Res- pondents	No. of Re- sponses per Responde nt	Total Annual Re- sponses	Time for Re- sponses in Minutes	Annual Burden Hours
Establishments are to prepare labels with descriptive designation and validated cooking instructions	555	15.227	8,451	13	1,831.05
Establishments are to develop validated cooking instructions	555	15.227	8,451	120	16,902
Total Reporting Burden	555	30.454	16,902	133	18,733.05

SUMMARY OF BURDEN Mechanically Tenderized Beef Products	
TOTAL NO. RESPONDENTS	555
AVERAGE NO. RESPONSES PER RESPONDENT	60.908
TOTAL ANNUAL RESPONSES	33,804
AVERAGE HOURS PER RESPONSE	2.417
TOTAL BURDEN HOURS	19,719

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6083, South Building, Washington, DC 20250.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper

performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB within 60 days of the publication date of this proposed rule.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this proposed regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

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To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY).

Additional Public Notification

FSIS will announce this proposed rule online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp.

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http://www.fsis.usda.gov/News_&_Events/Email_Subscription/.

Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 317

Food labeling, Food packaging, Meat inspection, Nutrition, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III as follows:

PART 317 LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for Part 317 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

2. Amend §317.2 by adding and reserving paragraphs (e) (1) and (2), and adding a new paragraph (e) (3) to read as follows:
§317.2 Labels: definition; required features.

* * * * *

(e) * * *

(3) Product name and required validated cooking instructions for needle- or blade-tenderized beef products. (i) Unless the product is destined to be fully cooked at an official establishment, the product name for a raw or partially cooked beef product that has been mechanically tenderized, whether by needle or by blade, must contain the term "mechanically tenderized" as a descriptive designation and an accurate description of the beef component.

(ii) The product name must be printed in a single font style, color, and size and must appear on a single-color contrasting background.

(iii) The labels on raw or partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions must contain validated cooking instructions, including the cooking method, that inform consumers that these products need to be cooked to a specified minimum internal temperature, whether the product needs to be held for a specified time at that temperature or higher before consumption to ensure that potential pathogens are destroyed throughout the product, a statement that the internal temperature should be measured by a thermometer.

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Done at Washington, DC on: June 3, 2013.

Alfred V. Almanza,
Administrator.